



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0853]

Tobacco Product Manufacturing Facility Visits

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products (CTP) is announcing an invitation for participation in its Tobacco Product Manufacturing Facility Visits.

This program is intended to give FDA staff an opportunity to visit facilities involved in the manufacturing of newly deemed tobacco products and their components and parts, including any related laboratory testing, and to observe the manufacturing operations of the tobacco industry.

The purpose of this document is to invite parties interested in participating in Tobacco Product Manufacturing Facility Visits to submit requests to CTP.

DATES: Submit either an electronic or written request for participation by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section IV of this document for information on requests for participation.

ADDRESSES: If your facility is interested in participating in Tobacco Product Manufacturing Facility Visits, please submit a request either electronically to <http://www.regulations.gov> or in writing to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Matthew Brenner, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903

New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, email:
CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31; 123 Stat. 1776) was signed into law, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing. The new provisions include, among other things, the authority to issue regulations related to tobacco product manufacturing practice in order to protect the public health and to assure that tobacco products are in compliance with the FD&C Act. Specifically, section 906(e) of the FD&C Act (21 U.S.C. 387f(e)) provides that in applying manufacturing restrictions to tobacco, the Secretary shall prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology.

CTP is instituting Tobacco Product Manufacturing Facility Visits to provide FDA staff with the opportunity to:

- Observe tobacco product manufacturing operations--from the receipt of raw materials to the distribution of newly deemed tobacco products, and
- Learn about the manufacturing practices and processes unique to your facility and newly deemed tobacco products.

This program will also inform FDA staff as they implement the tobacco provisions of the FD&C Act.

II. Description of the Tobacco Product Manufacturing Facility Visits

In this program, groups of FDA staff plan to observe the following facilities and their operations:

- Manufacturing facilities, including establishments that process, package, label, and distribute different types of newly deemed tobacco products (e.g., dissolvable products, gels, cigars, pipe tobacco, waterpipe tobacco products, and electronic nicotine delivery systems (ENDS) (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes) and liquid nicotine and flavors) (see 81 FR 28973, May 10, 2016),
- Laboratory facilities that perform tobacco testing (whether third-party or in-house), and
- Manufacturing facilities for tobacco products for further manufacturing into finished tobacco products (including, but not limited to, components, parts, flavors, casings, e-liquids).

Please note that Tobacco Product Manufacturing Facility Visits are not intended to include or replace official FDA inspections of facilities to determine compliance with the FD&C Act; rather, these facility visits are meant to educate FDA staff and improve their understanding of the tobacco industry and its manufacturing operations.

III. Site Selection

CTP plans to select sites from one or more of each of the following categories:

- Dissolvable products,

- Gels,
- Cigars,
- Pipe tobacco,
- Waterpipe tobacco products,
- ENDS (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes) and liquid nicotine and flavors,
- Tobacco laboratories,
- Importers of finished tobacco products,
- Distributors and wholesalers of regulated tobacco products, and/or
- Manufacturers of tobacco products for further manufacturing into finished tobacco products (including, but not limited to, components, parts, flavors, casings, e-liquids).

Final site selections will be based on the availability of CTP funds and resources for the relevant fiscal year, as well as the following factors, as applicable: (1) Compliance status of the requesting facility and affiliated firm; (2) whether the requesting facility or affiliated firm, if applicable, has a significant request or marketing application or submission pending with FDA; and (3) whether the requesting facility will be engaged in active manufacturing or processing during the proposed time of the visit. All travel expenses associated with Tobacco Product Manufacturer Facility Visits will be the responsibility of CTP.

IV. Requests for Participation

The request for participation should include the following identification information:

- The name and contact information (including address, phone number, and email) of your point of contact for the request;
- The physical address(es) of the site(s) for which you are submitting a request;

- The type of processes (e.g., manufacturing, laboratory practices, mixing, packaging, labeling, and distribution activities) performed at your facility;
- The type of tobacco products tested, processed, or manufactured at your facility; and
- A proposed program agenda.

Identify requests for participation with the docket number found in brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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